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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,378	10/25/2000	John Jianhua Chen	S63.2-9503	2980

490 7590 10/08/2003

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EXAMINER

HON, SOW FUN

ART UNIT PAPER NUMBER

1772

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,378

Applicant(s)

CHEN ET AL.

Examiner

Sow-Fun Hon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26,31,33 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26,31,33 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. In view of the Appeal Brief filed on 05/23/03, PROSECUTION IS HEREBY REOPENED. A detailed action is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Withdrawn Rejections

2. The 35 U.S.C. 103(a) rejections of claims 1-26, 31, 33, 36 have been withdrawn due to Applicant's arguments in Paper # 20 (filed 05/23/03).

New Rejections

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-7, 14, 24-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-10 of copending Application No. 09/885568. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in reciting a balloon comprising a polymer matrix and a fiber component wherein the fibers are distributed in a direction relative to the balloon axis, and wherein the fibers comprise liquid crystal polymer material (LCP).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-7, 12-19, 21, 24-26, 31, 33, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos (US 4,254,774) in view of Zdrahala (US 5,156,785).

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Boretos teaches a balloon catheter which has a one-piece unitary construction which minimizes the possibility of detachment or separation of portions thereof accidentally in a critical area of the body where harm may be incurred to the patient, such as in the area of the brain or lungs (column 2, lines 60-70). To form the balloon, the catheter tubing is heated locally in the area where the balloon is desired and then inflated (column 5, lines 40-70). Boretos teaches that the catheter tubing may comprise any suitable thermoplastic material such as polyurethanes and copolyester polymers (column 4, lines 35-45).

Boretos fails to teach the polymer fibril component distributed in the polymer matrix.

Zdrahala has an extruded catheter tubing which exhibits stiffness in the longitudinal direction as well as rotational stiffness and both may be varied along the length of the tubing (column 1, lines 55-70 and column 2, lines 1-5). The composition contains from 5 to 35 weight percent of the liquid crystal polymer (or from 95 to 65 weight percent of the polymer matrix component), and the matrix of the blend may be composed of polyurethanes, polyamides, polyesters and copolyester elastomers which are softer materials than the liquid crystal polymer (column 4, lines 15-35) so that they are either compliant or semi-compliant. The liquid crystal fibers are distributed in the matrix material diagonally to the longitudinal axis of the balloon and changes in orientation through the balloon material in a direction transverse to the longitudinal axis of the balloon (separate phase of liquid crystal plastic forms helical extending, separate fibrils within the extruded tubing with the fibers (fibrils) being dispersed in the structural plastic matrix) (column 5, lines 1-15). The fibers are thus cores of liquid crystal polymeric material coextruded with the matrix material (column 6, lines 35-22). Since the liquid crystal polymers are rather stiff in the solid state (column 3, lines 35-45) thus having higher tensile strength, the

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bulk elongation of the liquid crystal polymeric cores is less than the softer elastomeric matrix when oriented in the direction of the longitudinal axis.

Zdrhala teaches a liquid crystal polymer with a molecular weight of 100,000 made from polymerizing 30 weight percent of poly(ethylene terephthalate) prepolymer reacted with 70 weight percent of p-hydroxybenzoic acid (column 6, lines 1-50). In the absence of a clear factual showing, it is the examiner's position that the melting temperature of the liquid crystal polymer is about 250 °C or less, and in the absence of a showing of unexpected results, it is the examiner's position that the melting temperature of 230 °C or less is a result of routine experimentation.

The extruded liquid crystal polymer fiber core-containing material is laminated (coated) with a layer of non-liquid crystal polymer material such as softer polyurethanes on both sides (an exterior coating and additionally a coating of the inner lumen as well (column 4, lines 30-50).

The catheter tubing can have a body portion wherein the fibers are oriented substantially parallel to the longitudinal axis of the balloon (orientation to be substantially longitudinal to provide a section of relatively low rotational stiffness and relatively high longitudinal stiffness) (column 2, lines 40-60).

Since Zdrhala teaches that the fibers (fibrils) exhibit an aspect ratio of about 10 to 300, the aspect ratio being defined by the length of the fiber divided by its diameter (column 5, lines 15-30), in the absence of a showing of unexpected results, it is the examiner's position that the claimed range of the LCP (liquid crystal polymer) fiber diameter of from 0.01 to about 10 microns is a result of routine experimentation.

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Since Zdrahala teaches that the catheter tubing has longitudinal stiffness (column 7, lines 50-65), and since it is desirable for the balloon to have horizontal expansion and not longitudinal expansion, it is the examiner's position that it would have been obvious to one of ordinary skill in the art to limit the longitudinal expansion of the balloon to less than 5 % beyond the pre-inflation state.

Since Zdrahala teaches that the fiber reinforced catheter tubing has stiffness in the longitudinal direction as well as rotational stiffness and that both may be varied along the length of the tubing, it would have been obvious to one of ordinary skill in the art to have used the fiber reinforcement taught by Zdrahala in the invention of Boretos in order to obtain a balloon catheter with the desired variance in axial and rotational stiffness along its length.

7. Claims 20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos in view of Zdrahala as evidenced by Polymers (A Property Database).

Boretos has been discussed above and fails to teach the fiber-reinforcement of the balloon for a medical device.

Zdrahala has been discussed above and teaches that the fiber component is in a polyamide matrix. The example of the polyamide matrix component is given as nylon 12 (column 6, lines 45-55).

Polymers teaches that nylon 12 has a melting point range of around 170 to 190 °C (Page 2, Melting Temperature) which is within the claimed range of 140 to about 265 °C.

8. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos in view of Zdrahala as applied to claims 1-7, 12-19, 21, 24-26, 31, 33, 36 above, and further in view of Heino et al. (US 6,221,962).

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Boretos has been discussed above and fails to teach the fiber-reinforcement of the balloon catheter for a medical device.

Zdrahala has been discussed above and teaches the liquid crystal fiber-reinforcement of the catheter tubing, but fails to teach the compatibilizer.

Heino et al. is directed to liquid crystal polymer blends wherein the liquid crystalline polymer forms fibers which orient in the flow direction of the thermoplastic matrix melt, improving the tensile strength and modulus of elasticity of the solidified matrix (column 1, lines 20-40). The compatibilizer for the blends can be a block copolymer (column 3, lines 1-15).

Since Heino et al. teaches that the compatibilizer improves adhesion and dispersion of the liquid crystal polymer in the matrix, thus improving the impact strength of the composite (column 1, lines 20-70), it would have been obvious to one of ordinary skill in the art to have provided the compatibilizer as taught by Heino et al. in the liquid crystal polymer blend of Zdrahala for use in the invention of Boretos in order to obtain a balloon catheter with the desired impact strength as well as tensile strength and modulus of elasticity.

Response to Arguments

9. Applicant's arguments with respect to claims 1-26, 31, 33, 36 have been considered but are moot in view of the new ground(s) of rejection.


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Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

SH
Sow-Fun Hon
09/24/03


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

9/25/03